K022290

AUG 2 7 2002

Summary of Safety and Effectiveness Information

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter's Name: Donna A. Wolf
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714-6101

Date of Preparation: August 7, 2002

Name of Product: Protein S Ac

FDA Classification Name: Factor Deficiency Test

Predicate Device: STA® Staclot® Protein S kit (K913424)

Device Description:

Protein S Ac is a reagent intended for the quantitative determination of the functional activity of protein S in human plasma.

Protein Ca proteolytically cleaves F Va which is generated during the activation of the coagulation cascade by RVV (venom of Vipera russelli). In this reaction protein S acts as a cofactor which accelerates the reaction. As a result, the coagulation time increases proportionally to the activity of protein S in the sample. The addition of deficient plasma ensures that the test mixture has a sufficient supply of fibrinogen, Factor V and the other necessary coagulation factors.

Coagulation is triggered at the level of Factor X by the FX activator of RVV. FXa forms thrombin from prothrombin under the action of the remaining Factor Va. The resulting thrombin finally converts fibrinogen to fibrin.

Intended Use: For the quantitative determination of the functional activity of protein S in human plasma.

Comparison to Predicate Device:

Conclusion:

Split sample comparison between the Protein S Ac and the STA® StaClot® Protein S kit (K913424) gave a correlation coefficient of 0.919, slope of 0.961, and an intercept of +1.534 when tested with 239 patient samples spanning the range of the target population.

For normal plasma samples measured using the Sysmex® CA 1500, the resulting variation coefficients ranged between 3.6% and 5.1% within the series of measurements, and between 2.0% and 4.1% from day to day. Total precision ranged from 4.6 to 5.5%. For pathologically deficient plasma samples which were measured using the Sysmex® CA 1500, the resulting variation coefficients ranged between 4.7% and 9.2% within the series of measurements, and between 1.9% and 7.7% from day to day. Total precision ranged from 4.8 to 11.6%.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 27 2002

Ms. Donna Wolf
Senior Regulatory Affairs Specialist
Dade Behring, Inc.
514 GBC Drive
Newark, Delaware 19702

Re: k022290
Trade/Device Name: Protein S Ac
Regulation Number: 21 CFR § 864.7290
Regulation Name: Factor Deficiency Test
Regulatory Class: II
Product Code: GGP
Dated: July 12, 2002
Received: July 13, 2002

Dear Ms. Wolf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

Device Name: Protein S Ac

Indications for Use:

Reagent for the quantitative determination of the functional activity of protein S in human plasma.

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K022290

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-the-counter Use**_____
(Per 21 CFR 801.109)

(Optional format 1-2-96)